

response, Claims 1, 5, and 8-10 have been canceled. Claims 2-4, 6, and 7 have been amended, and newly submitted Claims 21 and 22 have been added. Applicants respectfully submit for the reasons set forth below that the rejections have either been overcome in view of the amendments or are improper for the following reasons.

At the outset, Applicants do not believe that the rejections are in proper format. In this regard, the Manual of Patent Examining Procedure (MPEP) specifically cautions an Examiner against making cumulative rejections and requests that the Examiner cite and rely on only the best references. Cumulative rejections make it difficult for Applicants to properly respond to the rejection. In the instant Office Action, a number of cumulative rejections are made.

Moreover, some claims have been rejected as being anticipated by a reference and then in the next paragraph of the Office Action as being obvious in combination with a different reference. Applicants submit this is not proper.

In this regard, the Patent Office has set forth in the Office Action a number of different 35 U.S.C. § 102 as well as § 103 rejections. Claims 1-9 stand rejected under 35 U.S.C. § 102(a) as being anticipated by *WO 96/08261*; Claims 1-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over *WO 96/08261* in view of U.S. Patent No. 5,006,361 ("*Cox*"); Claims 1-3, 6-8, and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,283,059 ("*Suzuki*"); Claims 1-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over *Suzuki* in view of *Cox* and U.S. Patent No. 4,943,437 ("*Kvanta*"); Claims 1-9 stand rejected under 35 U.S.C. § 102 as being anticipated by *EP 0159891*; Claims 1-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over *EP 0159891* in view of *Cox* and *Kvanta*; Claims 1-3 and 6-8 stand rejected as being anticipated by *WO 91/17672*; and Claims 1-20 stand rejected as being obvious under 35 U.S.C. § 103 over *WO 91/17672*.

Newly submitted Claim 21 is substantially a combination of original Claims 1, 5 and 10 and Claim 22 is substantially a combination of original Claims 1, 7 and 10.

With respect to the objections generally, none of the 35 U.S.C. § 102 rejections are made against

Claims 11, 16 or 19. Nor could any of the § 102 rejections have been posed against a combination of either Claims 1, 5 and 10 or 1, 7 and 10. Accordingly, in view of the amendments, the 35 U.S.C. § 102 rejections have been overcome. Therefore, Applicants respectfully request that all of the 35 U.S.C. § 102 rejections be withdrawn.

With respect to the 35 U.S.C. § 103 rejections, Applicants do not believe that a *prima facie* case of obviousness has been made against the remaining claims. With respect to *WO 96/08261*, this reference discloses the encapsulation of probiotic micro-organisms with resistant starches to cause transportation of the micro-organisms to the large bowel and to facilitate growth in the large bowel. There are a number of ways disclosed of allegedly accomplishing same. One method is to feed the resistant starch and an oil into an extruder (page 13, line 32-page 14, line 31). The extruder is operated at a low temperature (less than 70°C). Near the die, a suspension of the probiotic micro-organism and an oil is injected into the extruder. The mixture is then extruded through two millimeter orifices and granulated.

Because in *WO 96/08261*, and specifically the method set forth therein, no water is introduced into the extruder and the temperatures are low, gelatinization of the starch does not occur. Accordingly, in *WO 96/08261*, there is no disclosure of a gelatinized starch matrix; either inherently or explicitly. Each of the pending independent claims requires a gelatinized starch matrix.

Furthermore, since the mixture is then extruded through two millimeter orifices and granulated, small capsules are produced. Hence, there is no disclosure of kibbles or, in fact, even pet food. All of the pending claims are now limited to pet kibbles. Also, there is no disclosure of coating or filling kibbles with the probiotic micro-organisms.

WO 96/08261 has been combined with *Cox* in rejecting Claims 1-20 as being obvious; this, even though Claims 1-9 are allegedly anticipated by *WO 96/08261*. *Cox* discloses particles (pellets) that may be used in feed products for an animal's consumption including pet foods. The pellets are formed of an inner core of lipids surrounded by a water-insoluble alginate shell. The pellets may contain "optional

additives” such as “mineral supplements, vitamins, blood, yeast, fish oil, preservatives, medications including antibiotics and/or antifungals, antioxidants, visual attractants such as dyes, olfactorily enticing additives, gustatory enticing factors, and the like” (column 7, lines 53-58). Further, in column 21, lines 13-23, it is mentioned that the pellets may be “incorporated within the kibble structure or may be loosely admixed with kibbles to increase the palatability and nutritional value thereof.”

Cox makes no mention of probiotics. *Cox* therefore makes no suggestion that probiotics may be incorporated into lipid pellets. Further, it is not even clear whether or not probiotic micro-organisms would be able to survive the pelletization process of *Cox*. Moreover, *Cox* makes no disclosure of coating or filling pet kibbles; *Cox* merely discloses incorporating pellets within the kibble structure or loosely admixing same with the kibbles.

Therefore, even assuming that one skilled in the art would be led to combine *WO 96/08261* and *Cox*, no combination of these references would provide a pet kibble which has a coating or filling containing probiotic micro-organisms. At best, the combination would teach a pet kibble which contains pellets within its matrix, which in turn, contain probiotic micro-organisms. This is not what Applicants are claiming.

Regardless, Applicants also disagree that a person of ordinary skill in the art would be motivated to combine the teachings of *WO 96/08261* and *Cox*. In this regard, *WO 96/08261* formulates probiotic micro-organisms with resistant starch in order to deliver the micro-organisms to the large bowel and to facilitate growth in the large bowel. *Cox* formulates various substances into liquid pellets which have an alginate shell. This is done by a specific process in *Cox*.

There is nothing to suggest that the probiotic micro-organisms of *WO 96/08261* would survive the process of *Cox*. Furthermore, there is nothing to suggest that the probiotic micro-organisms of *WO 96/08261* would be able to escape the pellets of *Cox* and colonize the GI tract in view of the alginate shell. Furthermore, there is nothing to suggest that the resistant starch would be sufficiently bioavailable in the pellets of *Cox* to perform the function taught in *WO 96/08261*.

Applicants suggest that one skilled in the art would not combine *WO 96/08261* with *Cox*. One skilled in the art would believe that such a combination could destroy the functionality provided by the system of *WO 96/08261*. In this regard, there is no reason why one skilled in the art would want to include the composition into a lipid-alginate capsule. Neither the references, nor the art, provide any reason that one skilled in the art would believe that such a combination provides any likelihood of success.

Applicants respectfully submit that it appears that the Office Action has arbitrarily picked two divergent disclosures and randomly matched these disclosures. Of course, the test for obviousness is whether or not the art as a whole would suggest the combination being asserted by the Patent Office. Therefore, Applicants do not believe that *WO 96/08261* and *Cox* provide a *prima facie* case of obviousness against the pending claims. Therefore, Applicants respectfully request that the rejection be withdrawn.

Claims 1-20 stand rejected under *Suzuki* in view of *Cox* and *Kvanta*. Applicants respectfully submit for the reasons set forth below that the rejection is not er.

Suzuki discloses feed pellets. The feed pellets contain spore forming micro-organisms; some of which may be probiotic. These pellets are produced by first spraying or air drying a slurry of the starch component and the micro-organism. This provides starch/micro-organism particles similar to those of *WO 96/08261*. These particles are then combined with animal feed and pelleted "by a conventional method using a pelleting machine to obtain pellet-type feed" (column 4, lines 11-15).

Suzuki makes no disclosure of a pet kibble which has a gelatinized starch matrix. The Patent Office's reference to "gelatinization" is, it is respectfully submitted, not proper as it refers to a portion of *Suzuki* that describes the starch component which encapsulates the micro-organism, not the starch matrix of the kibble. Further, there is no disclosure of a pet kibble that has a coating or filling containing probiotic micro-organisms. In the feed pellets of *Suzuki*, the encapsulated micro-organisms are within the matrix of the pellets - this is inherent in the pelleting process of *Suzuki* where ingredients are fed into

the pelleting mill together.

As noted below, Applicants do not believe that one skilled in the art would be motivated to combine the *Cox* and *Suzuki* disclosures. Regardless, even assuming one skilled in the art would be led to combine *Suzuki* and *Cox*, the combination would not afford a pet kibble that has a coating or filling containing probiotic micro-organisms. At best, that combination would teach a feed pellet that contains the lipid pellets of *Cox* within the matrix. This is not Applicants' claimed invention.

In any event, Applicants disagree that one skilled in the art would be motivated to combine the teachings of *Suzuki* and *Cox*. *Suzuki* encapsulates micro-organisms with starch in order to enable the micro-organisms to survive the pelletization process. *Cox* formulates various substances into the lipid pellets that have an alginate shell. There is no suggestion in the art that the micro-organisms of *Suzuki* would survive the process of *Cox*. Further, there is no suggestion in the art that the lipid pellets of *Cox* would be able to protect the micro-organisms of *Suzuki* during pelletization. Indeed, just the opposite is most likely since the lipid pellets of *Cox* are unlikely to survive the pressures and temperatures of *Suzuki*'s pelletization process. Therefore, the combination of *Suzuki* and *Cox* is unlikely to work, and even if it did, would not provide the claimed invention.

Kvanta does not remedy the deficiencies of *Suzuki* and *Cox*. *Kvanta* discloses coating food stuffs or animal foods with a coating containing a biologically active material and an inert carrier. The inert carrier has the opposite polarity of the biologically active material.

In *Kvanta*, there is no disclosure of pet kibbles. *Kvanta* provides no disclosure of gelatinized starch matrix. Further, *Kvanta* provides no disclosure of probiotic micro-organisms. Therefore, no combination of *Kvanta* with *Suzuki* or *Cox* provides the claimed invention.

Still further, Applicants do not believe that *Kvanta* can be combined with *Suzuki* and *Cox*. *Suzuki* discloses feed pellets that contain starch encapsulated micro-organisms within their matrix. *Cox* discloses alginate-lipid pellets that may be included within the matrix of pet foods or mixed with pet foods. *Kvanta* discloses coatings that use an inert carrier having a polarity opposite to the biologically

active material. Accordingly, none of these disclosures are complimentary or suggest any combination. Indeed, they are largely mutually exclusive.

Accordingly, Applicants do not believe that the Patent Office has made out a *prima facie* case of obviousness over *Suzuki* in view of *Cox* and *Kvanta*.

Claims 1-20 also stand rejected under 35 U.S.C. § 103 as being unpatentable over *EP 0159891* in view of *Cox* and *Kvanta*. Applicants respectfully submit that this rejection is not proper.

EP 0159891 discloses particles that contain micro-organisms. The particles have a saccharide core coated by a suitable binding material. The micro-organisms are bound to the core by the binding material. There is no disclosure of a pet food in *EP 0159891*. There is no disclosure of a gelatinized starch matrix in *EP 0159891*.

Accordingly, even assuming one skilled in the art would be motivated to combine *EP 0159891* and *Cox*, which Applicants respectfully submit they would not, no combination of these references would provide a pet kibble that has a coating or filling containing probiotic micro-organisms.

Moreover, Applicants do not believe one skilled in the art would be motivated to combine *EP 0159891* and *Cox*. *EP 0159891* coats the particles with a binding material; especially a fat. *Cox* formulates various substances into lipid pellets that have an alginate shell. The purpose of the alginate shell of *Cox* is specifically to prevent any "strickiness" or "oiliness" - in other words, to avoid having a coating of a binding material. Further, the lipid pellets of *Cox* require droplets of alginate-lipid mixture to be dropped into an aqueous fixing agent (for example, calcium chloride). The particles of *EP 0159891* are not compatible with this process.

Accordingly, Applicants do not believe that one skilled in the art would be motivated to combine these two references as they would not be workable.

Applicants respectfully submit that *Kvanta* does not remedy the deficiencies noted above. As mentioned previously, there is no disclosure in *Kvanta* of pet kibbles, gelatinized starch matrix, or probiotic micro-organisms. Therefore, the combination of *EP 0159891*, *Cox* and *Kvanta* does not render

obvious the claimed invention.

Applicants also point out for the record, that a person skilled in the art is even less likely to combine *EP 0159891* and *Cox* with *Kvanta*. *EP 0159891* and *Cox* deal with mutually exclusive ways of encapsulating substances and *Kvanta* deals with coating of food products. Accordingly, Applicants question why one skilled in the art would be motivated to combine these references. Therefore, Applicants respectfully request that this rejection be withdrawn.

Claims 1-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over *WO 91/17672*. Applicants submit that this rejection is not proper. *WO 91/17672* discloses food products that are prepared by gelatinizing starch compounds including bran, fermenting the gelatinized starch with probiotic micro-organisms, and then formulated the fermented mixture in the food product. The food products are described as yogurts, "clabbered milk", "jelly-like", "porridge-like" and "liquid fluid". Further, in Example 8, page 13, it is mentioned that the food product may be used as an ingredient in other foods or in Example 9, page 13, that it may be freeze dried prior to being used as an ingredient. However, the foods are primarily intended to be chilled products - page 7, lines 23-31.

There is no disclosure in *WO 91/17672* of pet kibbles. There is no disclosure of gelatinized starch matrix having a coating or filling containing probiotic micro-organisms.

Therefore, even assuming *WO 91/17672* could be combined with *Cox*, which Applicants submit there is no motivation for such a combination, these references would not provide a pet kibble that has a coating containing probiotic micro-organisms. At best, the combination would lead to fermented products of *WO 91/17672* containing the lipid pellets of *Cox* within their matrix. This is not the claimed invention.

Furthermore, Applicants respectfully submit that one skilled in the art would not combine *WO 91/17672* and *Cox* except to fortify the fermented products of *WO 91/17672* with vitamins and minerals. Note in *WO 91/17672*, the micro-organisms cannot be encapsulated otherwise they would not be able to ferment the gelatinized starch.

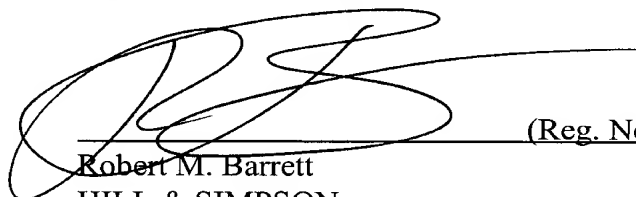
Moreover, combining *Suzuki* with combinations of *WO 91/17672* and *Cox* does not provide a pet kibble which has a coating containing probiotic micro-organisms. At the very best, the combination would teach fermented products of *WO 91/17672*, containing the lipid pellets of *Cox* within their matrix, and the starch capsules of *Suzuki* within their matrix. This is not the claimed invention.

Still further, one skilled in the art would not attempt to combine references teaching fermented chilled products, alginate lipid capsules, and feed products containing starch. There is no reason why one skilled in the art would even attempt such a combination.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent and earnestly solicit an early allowance of same.

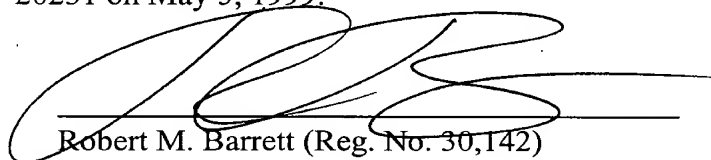
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